UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,189	03/28/2001	Raghavendra Manikanahally Papannegowda	U 013354-4	3824

7590 07/02/2002

Ladas & Parry
26 West 61 Street
New York, NY 10023

EXAMINER
MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/02/2002 4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,189	PAPANNEGOWDA ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "lipase enzyme" is redundant because a lipase is an enzyme. To recite a "lipase" is sufficient. Steps a) and c) of the claim is confusing since "the said" is confusing. Applicant is asked to either use, "the" or "said" but not both. In step b), the ratios of 1:10, 1:100 and so forth should be put in a markush group since applicant appears to be choosing one of the ratios for the claim. Step c) is confusing because it is not clear what "adding it to a substrate" refers to. Also in step c, it is confusing to state "an activator such as $CaCl_2$". It would be clearer if applicant either stated using $CaCl_2$ or stated it in a dependent claim as being a specific activator. Step d) is confusing in that how does incubating for 4 hours "check for activity" ?

Claim 2 is not an appropriate markush group since it does not use the language, "a salting out agent selected from the group consisting of ....". Claim 4 has a similar problem with its markush group.

In claim 5, "the mixture" has no antecedant basis. Further, what is the 5 % relative to ?

Claim 6 is confusing since it is not clear if the ligand comprises an aromatic boro compound or the compound and something else.

Claim 8 fails to further limit claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vainio et al. or Garner in view of Gargouri et al. and further in view of JP 05001297 ('297-abstract), JP 56015643 ('643-abstract) or Nagoh et al., Boyer and Oester et al.

Vainio teaches deactivating (inhibiting) lipase from bovine milk with benzene boronic acid using NaCl and Tris-HCl and sodium phosphate buffers, see abstract and page 387.

Garner teaches inhibiting porcine pancreatic lipase with benzene boronic acid, tributyrin, NaCl, see abstract, pages 5064-5065.

The references do not teach using a lipase from rice bran, dialysis, size-exclusion chromatography, using $CaCl_2$, ammonium sulfate.

Vainio also does not teach using tributyrin.

Gargouri et al. teaches inhibiting lipases using tributyrin, ammonium sulfate and $CaCl_2$, see abstract, page 327, fig. 4, table 1.

The JP references and Nagoh (see abstract) teach that rice bran lipases are well known.

Oester teaches that lipase is routinely purified by size exclusion chromatography, see abstract.

Boyer teaches that dialysis is one of the oldest procedures applied to the purification and characterization of biomolecules, pages 44-48, especially page 44. Boyer on page 46 also mentions the use of ammonium sulfate for the purification of proteins and then using dialysis.

It would have been obvious to one of ordinary skill in the art to deactivate (inhibit) a rice bran lipase instead of the lipases of Vainio and Garner since the JP references and Nagoh teach that rice bran lipases are well known in the art and to use rice bran lipase instead of the references of the primary references is simply the choice of the artisan in an effort to optimize the desired results. Whether the skilled artisan uses one lipase or another, it is simply the choice of the artisan to use a well known lipase which is cheap to manufacture and easy to process, such is reflected by the references.

To use dialysis is obvious since Boyer makes it clear that dialysis is well known for the purification of biomolecules.

To use size exclusion chromatography would also have been obvious since Oester teaches that lipases are routinely purified by size exclusion chromatography.

To use $CaCl_2$ and ammonium sulfate is also obvious since Gargouri et al. teaches inhibiting lipases using tributyrin, ammonium sulfate and $CaCl_2$.

To use tributyrin in Vainio would have been obvious since Gargouri teaches inhibiting lipases using tributyrin, ammonium sulfate and $CaCl_2$.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ranges instantly claimed), as well as using a type of lipase or salting out agent, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abouakil et al. in view of Vainio et al. or Garner and further in view of Gargouri et al. and JP 05001297 ('297-abstract), JP 56015643 ('643-abstract) or Nagoh et al., Boyer and Oester et al.

Abouakil teaches inhibiting human milk lipase with phenyl boronic acid, tributyrin, using NaCl and Tris-HCl and sodium phosphate buffers, see abstract and page 216.

Abouakil does not teach using a lipase from rice bran, dialysis, size-exclusion chromatography, using $CaCl_2$, ammonium sulfate or using specifically benzene boronic acid.

Gargouri et al. teaches inhibiting lipases using tributyrin, ammonium sulfate and $CaCl_2$, see abstract, page 327, fig. 4, table 1.

The JP references and Nagoh (see abstract) teach that rice bran lipases are well known.

Oester teaches that lipase is routinely purified by size exclusion chromatography, see abstract.

Boyer teaches that dialysis is one of the oldest procedures applied to the purification and characterization of biomolecules, pages 44-48, especially page 44. Boyer on page 46 also mentions the use of ammonium sulfate for the purification of proteins and then using dialysis.

It would have been obvious to one of ordinary skill in the art to deactivate (inhibit) a rice bran lipase instead of the lipase of Abouakil since the JP references and Nagoh teach that rice bran lipases are well known in the art and to use rice bran lipase instead of the references of the primary references is simply the choice of the artisan in an effort to optimize the desired results. Whether the skilled artisan uses one lipase or another, it is simply the choice of the artisan to use a well known lipase which is cheap to manufacture and easy to process, such is reflected by the references.

To use dialysis is obvious since Boyer makes it clear that dialysis is well known for the purification of biomolecules.

To use size exclusion chromatography would also have been obvious since Oester teaches that lipases are routinely purified by size exclusion chromatography.

To use $CaCl_2$ and ammonium sulfate is also obvious since Gargouri et al. teaches inhibiting lipases using tributyrin, ammonium sulfate and $CaCl_2$.

To use benzene boronic acid in Abuakil would have been obvious since both Vainio and Garner teach using benzene boronic acid to inhibit lipases. They show success with using such an inhibitor and thus establish that one of ordinary skill in the art would have been motivated to use such a boronic acid instead of phenyl boronic acid since benzene is a well known alternative to the phenyl form.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ranges instantly claimed), as well as using a type of lipase or salting out agent, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller
Examiner
Art Unit 1651

MVM
June 28, 2002